



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ASTATKE *et al.*

Appl. No. 09/608,066

Filed: June 30, 2000

For: **Compositions and Methods for
Enhanced Sensitivity and Specificity
of Nucleic Acid Synthesis**

Confirmation No.: 1120

Art Unit: 1634

Examiner: Taylor Cleveland, J.

Atty. Docket: 0942.4990001/RWE/BJD

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Reply Under 37 C.F.R. § 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In reply to the non-final Office Action dated March 29, 2002 (Paper No. 17), Applicants submit the following remarks. In accordance with 37 C.F.R. § 1.121 and MPEP § 714, appropriate remarks and arguments are provided herein starting on a separate page since no amendments to the specification or claims are sought.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Remarks

I. Status of the Claims

Claims 81 and 82 are pending in the application, with claim 81 being the sole independent claim.

II. Summary of the Office Action

In the Office Action dated March 26, 2002, the Examiner has made one rejection of the claims. Applicants respectfully offer the following remarks to overcome or traverse this rejection.

III. The Rejection Under 35 U.S.C. § 102(e) Over Goff Is Traversed

In the Office Action at pages 2-3, sections 2-4, the Examiner has rejected claims 81 and 82 under 35 U.S.C. § 102(b) as being anticipated by Goff *et al.*, U.S. Patent No. 4,943,531 (Doc. "A" cited on the Form PTO-892 attached to Paper No. 17; hereinafter "Goff"). Applicants respectfully traverse this rejection.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). This burden is not satisfied by the disclosure of Goff, which therefore cannot and does not anticipate the claims as currently presented.

As the Examiner has noted, claims 81 and 82 are drawn to methods of producing cDNA molecules from mRNA molecules using one or more reverse transcriptases in the

presence of one or more double stranded nucleic acid inhibitors. In contrast, Goff does not disclose the use of inhibitors of reverse transcriptase activity, wherein the inhibitors are double stranded nucleic acid molecules. In making this rejection, the Examiner appears to have interpreted the term “double stranded nucleic acid inhibitors” (as recited in claims 81 and 82 as originally filed) to refer to an inhibitor of the production of double nucleic acid molecules. This interpretation would explain why the Examiner considers actinomycin D, which is disclosed in Goff as binding to double-stranded nucleic acid molecules thereby inhibiting second strand synthesis, to be a “double stranded nucleic acid inhibitor.” *See Office Action* at pages 2-3. However, this interpretation is not what is meant by the term “double stranded nucleic acid inhibitor” as that term is used in claims 81 and 82. Instead, as one of ordinary skill would readily understand from the guidance provided in the specification, this term refers to double stranded nucleic acid molecules *that are themselves inhibitory -- i.e.,* nucleic acid molecules that bind to and reduce, inhibit or prevent the activity of a polymerase or reverse transcriptase enzyme during nucleic acid synthesis, sequencing or amplification catalyzed by the enzyme. This usage is consistent with the definition of “inhibitory nucleic acids” that is provided in the present specification, for example at page 26, line 12, to page 28, line 4, and throughout the Examples at pages 40-56. Hence, as one of ordinary skill would readily understand, the inhibitors used in the compositions of claims 81 and 82 are *themselves* inhibitory double stranded nucleic acid molecules. Thus, Actinomycin D, the only “inhibitor” specifically disclosed in the section of Goff relied upon by the Examiner, is not a “nucleic acid inhibitor” as this term is defined and used in the present specification and claims. Accordingly, under *Kalman*, Goff cannot and does not anticipate claims 81 and 82.

In view of the foregoing remarks, reconsideration and withdrawal of the rejection of claims 81 and 82 under 35 U.S.C. § 102(b) over Goff are respectfully requested.

IV. Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider and withdraw all of the outstanding rejections.

It is believed that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt entry and favorable consideration of the foregoing amendments and remarks, and allowance of all pending claims, are earnestly solicited.

Respectfully submitted,

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